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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/474,478	12/29/1999	B. JACK LONGLEY	58434-A/JPW/	2296

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EXAMINER
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GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

22

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/474,478

Applicant(s)

LONGLEY, B. JACK

Examiner

Ralph Gitomer

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 50-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

The RCE request and amendment received 3/17/03 have been entered and claims 50-57 are currently pending in this application. In claim 57 line 2, "administration" may be intended to be "administering". Please update the preamble of the specification regarding the issued parent application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Columbo in view of Mohammadi.

What has been searched and considered here is:

A method of preventing or treating cutaneous inflammation by inhibiting a KIT protein.

Columbo (J of Immunology) entitled "The Human Recombinant c-kit Receptor Ligand, rhSCF, Induces Mediator Release From Human Cutaneous Mast Cells and Enhances IgE Dependent Mediator Release From Both Skin Mast Cells and Peripheral Blood Basophils" teaches in the abstract, a ligand for the c-kit proto oncogene receptor, a member of the tyrosine kinase receptor class, and the effects of c-kit receptor ligand

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stem cell factor on the release of inflammatory mediators from human skin mast cells. There were effects on mast cells related to human allergic reactions and SCF may modulate mast cells function under physiologic conditions. On page 604 column 1, antibodies which recognize human c-kit receptor is shown. On page 606 column 2 last paragraph bridging to 607, the antibodies against c-kit receptor and their effects were discussed.

The claims differ from Columbo in that they are directed to preventing or treating specifically where Columbo is measuring effects.

Mohammadi (Science) entitled "Structures of the Tyrosine Kinase Domain of Fibroblast Growth Factor Receptor in Complex with Inhibitors" teaches on page 955, protein tyrosine kinases are critical components of signaling pathways and selecting inhibitors have considerable therapeutic value.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to specifically treat with inhibitors as taught by Mohammadi in the method of Columbo because the inflammatory effects related to c-kit and that such effects are modifiable are taught by Columbo. Mohammadi is directed to inhibiting the same pathways as Columbo for therapeutic reasons. The connection between c-kit and cutaneous inflammation is clearly shown by Columbo. To select a known antibody such as ACK2 in view of Columbo who selects other antibodies would have been obvious because it would have the expected result.

Applicant's arguments filed 11/25/02 have been fully considered but they are not persuasive.

Applicant argues that Columbo describes in vitro experiments in contrast to the claimed method which is directed to in vivo methods. One cannot base in vivo methods on in vitro experiments because they are not completely predictable and are merely an incentive to experiment. Mohammadi does not teach a mast cell system.

It is the examiner's position that the in vitro experiments of Columbo are highly suggestive of inhibiting the stem cell factor signaling pathway to treat cutaneous inflammation which is why the study was performed. One routinely bases in vivo methods upon in vitro experiments which is why in vitro experiments are performed and one would have a high expectation of success in doing so. Mohammadi was cited to teach the therapeutic value of inhibiting tyrosine kinases for treating.

Claims 50-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting the KIT protein in mice by administering ACK2 monoclonal antibodies as a form of treating, does not reasonably provide enablement for preventing or treating cutaneous inflammation in humans with any antibody that inhibits kit. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large number of inoperative conditions and antibodies for both treating and preventing claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances or conditions encompassed by the claims would work, especially for preventing.
3. Presence of working examples are only for a single specific antibody and extension to other antibodies has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related conditions and antibodies are not effective for the claimed functions, especially for preventing.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of conditions and antibodies.
8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The claimed invention is directed to preventing or treating cutaneous inflammation in various animals, including humans specifically, with antibodies that inhibit kit. Claim 57 includes a number of types of administration that are not taught in the specification.

Applicant's arguments filed 11/25/02 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches administering an antibody to mice to prevent or treat cutaneous inflammation.

It is the examiner's position that the specification does not enable one of skill in this art to make and use the invention as elected. For example, no specific compounds are shown to be administered to any person for a specific function and the results of the administration determined. The present specification on page 9 directed to Fig. 8 does not appear to be directed to cutaneous inflammation and does not enable treating humans.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Longley (6,576,812) is a parent patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Ralph Gitomer  
Primary Examiner  
Art Unit 1651

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RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200